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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,964	10/22/2001	Shin Nakamura	011361	8556

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EXAMINER	
BARTON, JEFFREY THOMAS	
ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/982,964	NAKAMURA ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Barton	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,7-10 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,7-10 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 April 2005 has been entered.

Response to Amendment

2. The amendment filed on 26 April 2005 does not place the application in condition for allowance.

Status of Rejections Pending Since the Office Action of 26 January 2005

3. All rejections of claims 3 and 4 are withdrawn due to cancellation of the claims.

4. The rejection of Claim 8 under 35 U.S.C. §112(2) is withdrawn due to Applicants' amendment.

5. The rejection of claim 5 under 35 U.S.C. §103(a) as obvious over Adourian et al in view of Smith et al, Burd, and Kambara is maintained.

6. The rejection of claim 7 under 35 U.S.C. §103(a) as obvious over Adourian et al in view of Smith et al, Burd, Kambara, and Manian is maintained.

7. The rejection of claims 8 and 9 under 35 U.S.C. §103(a) as obvious over Adourian et al in view of Smith et al, Burd, Kambara, and Uchigaki et al is maintained.

8. The rejection of claims 10 and 12 under 35 U.S.C. §103(a) as obvious over Adourian et al in view of Menchen et al is maintained.

Claim Rejections - 35 USC § 103

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claim 5 rejected under 35 U.S.C. 103(a) as being unpatentable over Adourian et al in view of Smith et al, Burd, and Kambara.

Adourian et al disclose an electrophoretic apparatus that comprises: an electrophoretic member in which a plate-shaped member thereof has a plurality of passages formed therein (Figures 10 and 11A, channels 152 and 194; Column 15, lines 14-41); holes reaching the passage formed at positions corresponding to both ends of the passage, on one surface of the plate-shaped member (Figure 11A, wells 190, 192, 194, 196; Column 15, lines 41-45; Figure 8A-C; Column 13, lines 24-32; Figure 7, openings 126 and 130); voltage applying parts for applying voltages across the passages of the electrophoretic member (Figure 7; Column 13, lines 14-19; Cathode and anode reservoirs in Figure 10; Column 15, lines 41-45); a detecting part for detecting a specimen present in the passages of the electrophoretic member (Figure 11B, detector 202; Column 15, lines 56-61; Column 17, lines 22-33); wherein the

detecting part consists of a fluorescent light-detecting device for detecting light in a detecting range (Column 17, lines 22-33; Column 18, lines 27-31)

Adourian et al do not explicitly disclose a specimen-injection monitor mechanism for detecting a specimen at a site where a specimen is injected into the passage, wherein the mechanism is installed separately from the detecting part. Adourian et al also do not explicitly disclose the use of a fluorescent light-detecting device comprising: a first optical system for focusing light from a detecting range into a slit hole for image formation, and a second optical system provided with a reflection-type diffraction grating, for separating the light from the slit hole and focusing the light onto a detecting element for image formation.

Smith et al disclose a capillary electrophoresis apparatus that includes a fluorescent light-detecting device that comprises: a first optical system for focusing light from a detecting range into a slit hole for image formation (Column 7, line 1 – Column 8, line 8; Figure 1A shows all components); a second optical system provided with a reflection-type diffraction grating, for separating the light from the slit hole and focusing the light onto a detecting element for image formation (Figure 1A, slit 121, grating 120; Column 8, line 1 – 8); and the second optical system consisting of only a concave reflection-type diffraction grating (grating is only component between slit and detector, see Figure 1A; Column 8, lines 9-16)

Burd discloses a capillary electrophoresis device that includes a sample-injection monitor detector (Figure 1, window 61) in addition to the downstream detector. (Window 60) (Column 4, line 59 - Column 5, line 22)

Kambara discloses splitting the beam of a light source in order to facilitate simultaneous detection at multiple sites in a capillary electrophoretic system while using a single source. (Figure 15; Column 31, lines 19-28)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of Adourian et al by replacing the light source and optics of their detector with the light source and optics of Smith et al, because Smith et al teach the usefulness of this scanning detector in efficiently monitoring multiple separation lanes. (Column 2, line 64 - Column 3, line 9)

It would also have been obvious to one having ordinary skill in the art at the time of the invention to further modify the combination of Adourian et al and Smith et al by including a separately-installed detector for specimen-injection monitoring, as taught by Burd, because Burd teaches the usefulness of such an injection monitor in coordinating other functions of the apparatus. (Column 5, lines 6-22) Similar functions (i.e. sequential injection, rotation of the device; Column 15, lines 51-56) are disclosed by Adourian et al.

It would also have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Adourian et al, Smith et al, and

Burd by using a single light source with a beam splitter for the plural detectors, as taught by Kambara, because it would simplify device operation and avoid variability in light source function.

11. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adourian et al, Smith et al, Burd, and Kambara as applied to claim 5 above, and further in view of Manian.

Adourian et al, Smith et al, Burd, and Kambara disclose a combination as described above.

None among Adourian et al, Smith et al, Burd, and Kambara explicitly disclose a fluorescence detection system that uses an LED light source.

Manian et al disclose a fluorescence detector for use in capillary electrophoresis that uses an LED light source (Column 4, lines 62-66)

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the combination of Adourian et al, Smith et al, Burd, and Kambara by using an LED light source for the detector, as taught by Manian et al, because it would be less expensive and more rugged than a laser.

12. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adourian et al, Smith et al, Burd, and Kambara as applied to claim 5 above, and further in view of Uchigaki et al.

Adourian et al, Smith et al, Burd, and Kambara disclose devices as described above. Adourian et al further disclose a control part that causes the voltage applying part to supply a voltage for guiding a specimen to an intersection between the specimen injection passage and the separation passage. (See Figure 8A-C) Burd also discloses using detected phenomena to actuate other functions of the device. (Column 5, lines 6-22)

None among Adourian et al, Smith et al, Burd, or Kambara explicitly disclose a control part that can stop the apparatus in case of nonuniform specimen distribution (Claim 8) or failure to inject a sample from the specimen injection passage to the separation passage. (Claim 9)

Uchigaki et al disclose a liquid analysis device that includes means for shutting down an analysis in case a pipetting step (injection step) is not correctly carried out. (Column 12, lines 50-55) Detection of such a situation can be carried out by optical means (Column 8, line 54 – Column 9, line 2)

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the combination of Adourian et al, Smith et al, Burd, and Kambara by creating a control program that would shut down the analysis if there was an injection irregularity detected at the injection site, as taught by Uchigaki et al, because it would increase efficiency by preventing time lost in unreliable analyses, and because Burd suggest such automatic actuation based on phenomena detected by the injection monitor.

13. Claims 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adourian et al in view of Menchen et al.

Adourian et al disclose an electrophoretic apparatus that comprises: an electrophoretic member in which a plate-shaped member thereof has a plurality of passages formed therein (Figures 10 and 11A, channels 152 and 194; Column 15, lines 14-41); holes reaching the passage formed at positions corresponding to both ends of the passage, on one surface of the plate-shaped member (Figure 11A, wells 190, 192, 194, 196; Column 15, lines 41-45; Figure 8A-C; Column 13, lines 24-32; Figure 7, openings 126 and 130); voltage applying parts for applying voltages across the passages of the electrophoretic member (Figure 7; Column 13, lines 14-19; Cathode and anode reservoirs in Figure 10; Column 15, lines 41-45); a detecting part for detecting a specimen present in the passages of the electrophoretic member (Figure 11B, detector 202; Column 15, lines 56-61; Column 17, lines 22-33); an electrophoretic medium filling mechanism for filling the passages and reservoirs with an electrophoretic medium, through the reservoirs of the electrophoretic member (Column 10, lines 32-39; Column 21, lines 15-27 – both methods can fill reservoirs, and it might be unavoidable given the narrowness and geometry of the channels and the lack of disclosure of means to avoid reservoir-filling); a specimen injection mechanism for injecting a specimen into one of the reservoirs (Column 15, lines 43-45 and 51-56); a buffer-liquid injecting mechanism for injecting buffer liquid into all reservoirs of an electrophoretic member (Figure 4; Column 10, line 59 - Column 11, line 10; Column 21, lines 15-49); and a

control part for controlling the electrophoretic apparatus, including the mechanisms, so that they all may operate automatically. (Figures 1 and 4, controllers 30 and 110)

The injection mechanism of Adourian et al, a multi-channel pipetting station 100 shown in Figure 4, is disclosed as being used for simultaneous injection of liquid into several reservoirs. (Column 11, lines 4-10) Regarding the liquid injected prior to sample loading (Column 11, lines 7-10), this would be buffer solution.

Relevant to claim 10, Adourian et al do not explicitly disclose an electrophoretic medium-sucking mechanism for removing electrophoretic medium contained in the reservoirs. Relevant to claim 12, Adourian et al do not explicitly disclose a specimen sucking mechanism for removing specimen left in the reservoirs after the specimen is injected into the passages.

Menchen et al disclose a capillary electrophoresis apparatus that includes a reservoir equipped with a vacuum system for drawing fluids from the reservoir (Figure 10, vacuum system 86, tube 84; Column 17, lines 63-66) Such a vacuum could remove either specimens or electrophoretic medium from the reservoir.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Adourian et al by adding a vacuum mechanism for withdrawing fluids from the reservoirs, as taught by Menchen et al, because it could conserve limited sample volumes or facilitate full automation by cleaning the reservoirs of gel prior to sample injection.

In such a combination, it would also be obvious to control the vacuum mechanism by the same control part as the rest of the apparatus, for ease of operation.

Regarding the limitation to a buffer liquid-injection mechanism for injecting a buffer simultaneously into all reservoirs of an electrophoretic member, if the disclosure at Column 11, lines 4-10 is not considered to be explicit disclosure, the Examiner considers that one having ordinary skill in the art would have immediately envisioned simultaneous loading of all injection ports 126, since a skilled artisan would have understood that such parallel operations would increase the efficiency of the system.

Response to Arguments

14. Applicant's arguments filed 26 April 2005 have been fully considered but they are not persuasive.

Applicant argues that the combination relied upon in the rejection of claim 5 would not have been obvious to one having ordinary skill in the art, with specific arguments against a combination of Kambara with Burd. (Amendment Page 7, 1st and 2nd full paragraphs) This is not the combination that was argued in the rejection. The combination was made as modifications to Adourian et al based on the teachings of each successive reference. The Examiner respectfully maintains that one having ordinary skill in the art would be motivated to modify the system of Adourian et al and Smith et al by including a detector at the injection area, as taught by Burd, for the reasons described above. One skilled in the art would have recognized that a detector can be placed anywhere in the channel system, and Burd teaches the advantageous placement of a detector at the injection site. Furthermore, in such a system comprising plural detectors, it would have been obvious to use a single light source with a beam

splitter for irradiation of each site, again for the reasons described above. The advantageousness of using a single light source with a beam splitter for detection at multiple locations (e.g. no variability in source intensity or wavelength) would have been well known to one having ordinary skill in the art.

Applicant further argues that the amendments made to claim 10 distinguish the buffer liquid-injection mechanism of the instant claim over that of Adourian et al. The Examiner respectfully disagrees with Applicant's interpretation of the disclosure of Adourian et al at Column 11, lines 4-10. The multi-tip pipetter is described as follows: "The fluid transfer device 100 (e.g. a multi-tip pipetter) is capable of transferring multiple sample sources 104, in parallel/simultaneously, to one or more test modules 32. Additionally, the fluid transfer device 100 may operate as an injection device to preload the test modules with fluid prior to sample loading." The use of a multi-tip pipetter to load one test module, of the type shown in Figure 6, appears to point towards the filling of each injection port 126 simultaneously, given the disclosure of simultaneous fluid transfer. If this is not considered to be explicit disclosure, the Examiner considers that one having ordinary skill in the art would have immediately envisioned simultaneous loading of all injection ports 126, given this disclosure, as a skilled artisan would have understood that such parallel operations would increase the efficiency of the system. The chip shown in Figure 6 of Adourian et al shows no reservoirs other than the injection ports 126, and thus this would meet the limitation to "all reservoirs" of the instant claim. The claim language does not reflect any considerations of the water head

difference, and accordingly this cannot be taken into consideration in determining patentability.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB
May 11, 2005

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